REMARKS

A. THE OFFICIAL ACTION SUMMARIZED

Initially, in the above-entitled Official Action, the Examiner objected to the misnumbering of claims 14-18, which have been renumbered 15-19 by amendment hereof.

On the art, the Examiner rejected each of claims 1-19 under 35 U.S.C. § 103(a) as being purportedly unpatentable over the cited U.S. Patent No. 4,264,577 to Zimmerman, et al., and with the following comments:

> "The Zimmerman *et al.* patent teaches the use of alkyl or alkenyl sulfate salts, such as sodium n-tetradecyl sulfate as a contraceptive agent (See Column 2, Line 60 to Column 3, Line 8; and Examples). These salts are believed to interfere with the action of hyaluronidase and/or acrosin, which are sperm acrosomal enzymes known to be responsible for penetration through the outer layers of an ovum (See Column 8, Lines 25-54). In order to impart effectiveness by ensuring a proper level of the active agent is present within a patient, continuing administration from an intrauterine device is disclosed.
>
> The instantly claimed invention cannot be found patentable above the disclosure of the prior art. That the instantly claimed compositions and methods are now claimed to be usable by males is a property that is, in the position of the examiner, inherently present in the prior art. The same compound accomplishes the same function as a contraceptive, by the same action of inhibiting enzymes to prevent penetration by sperm through the outer layers of an ovum. See MPEP 2112. Regarding claims directed to particular dosage forms, the prior art acknowledges the existence of such routes of administration of contraceptive agents, by the use of pills, injections, or subdermal implants (See Column 1, Lines 1-62). As such, these claims are not considered to be novel. Thus, the instantly claimed invention is *prima facie* obvious." Pgs. 2-3 of the Official Action.

The applicant respectfully traverses the above rejections. More specifically and most respectfully, the applicant disputes the Examiner's contentions on purported inherency, of the purported teaching of the cited prior art, any purported comments regarding "acknowledged prior art," the Examiner's comment (and without specific rejection under § 102) of lack of novelty, and the Examiner's conclusion that a *prima facie* case of obviousness has allegedly been established.

B. APPLICANT'S RESPONSES

Initially, the applicant expresses his appreciation to the Examiner for his careful search and examination, and most helpful comments.

Please cancel previous claim 15 (now renumbered claim 16) as being substantially duplicative.

The claims have been amended (a) to record specifically the Examiner's objection to previous claims 14-18, and (b) to more specifically describe the invention, in that the defined substances are to be used in administration to the male. Attached hereto is the Declaration of the inventor, Ronald Zimmerman, Ph.D., in regard *inter alia* to the teachings of the cited prior art, as bearing on the Examiner's conclusion of obviousness of each of presently pending claims 1-15, 17-19. Insofar as the Examiner has stated "as such, these claims are not considered to be novel," the Examiner is believed to have referred to obviousness under Section 103, rather than novelty under Section 102. Confirmation of same is respectfully solicited.

The contents of the Declaration of Dr. Zimmerman are respectfully incorporated into these comments.

It is believed to be helpful to review the appropriate standards for rejections, if any, under 35 U.S.C. § 103. In that regard, the MPEP states at § 706.02(j), as follows:

> **706.02(j) Contents of a 35 U.S.C. 103 Rejection**
>
> **35 U.S.C. 103** authorizes a rejection where, to meet the claim, it is necessary to modify a single reference or to combine it with one or more other references. After indicating that the rejection is under **35 U.S.C. 103**, the examiner should set forth in the Office Action:

(A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,

(B) the difference or differences in the claim over the applied reference(s),

(C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and

(D) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification.

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To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See **MPEP § 2143 - § 2143.03** for decisions pertinent to each of these criteria.

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). See **MPEP § 2144 - § 2144.09** for examples of reasoning supporting obviousness rejections.

Where a reference is relied on to support a rejection, whether or not in a minor capacity, that reference should be positively included in the statement of the rejection. See *In re Hoch,* 428 F.2d 1341, 1342 n.3 166 USPQ 406, 407 n. 3 (CCPA 1970).

In summarization of the attached Declaration of Dr. Zimmerman, each of presently pending claims 1-15, 17-19 is directed to use of certain substances as defined in the claims for application (a) to a male, and (b) orally, transdermally, or subcutaneously. The cited prior

art, the '577 Zimmerman *et al.* patent, teaches application of specified compounds (a) to the female, and (b) by insertion *in utero*. Manifestly, the differences in the environment of the male *in vivo,* as contrasted with the female *in utero,* are dramatic. Moreover, the teaching of oral administration in the cited '577 Zimmerman *et al.* patent at Col. 1, ll. 1-62 deals with (1) oral administration, (2) to the female, and (3) administration of certain vastly different compounds. Most clearly, there is no teaching or suggestion in the cited '577 Zimmerman *et al.* patent that the subject sulfate salt compounds set forth in presently pending claims 1-15, 17-19 would be expected to be useful for (a) administration *in vivo*, whether orally, transdermally, subcutaneously or otherwise, and (b) administration to the male.

CONCLUSION

In view of the submission of amendments and comments hereinabove, it is respectfully submitted that each of present pending claims 1-15, 17-19, as amended, is allowable over the cited prior art, and a early Notice of Allowance is respectfully solicited.

Respectfully submitted,

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